K110159

MAY 12 2011

510(K) SUMMARY

Medical Compression Systems (DBN) Ltd

ActiveCare+SFT® System

7.1.1 Applicant's Name:

Medical Compression Systems (DBN) Ltd.
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Or Akiva 30600, Israel
Tel: +972 (4) 6266630
Fax: +972 (4) 6266640
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7.1.2 Contact Person:

Orly Maor
25A Sirkin Street
Kfar Saba 44421, Israel
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Fax: +972-153-9-7453607
oram.ma@gmail.com

7.1.3 Date Prepared:

January 10, 2011

7.1.4 Trade Name:

ActiveCare+SFT® System (ActiveCare®++)

7.1.5 Classification Name:

Sleeve, Limb, Compressible

7.1.6 Classification:

Class II; Product Code JOW;
Regulation No. 870.5800
Panel: Cardiovascular Devices

7.1.7 Predicate Devices

Medical Compression Systems (DBN) Ltd. ActiveCare+SFT® System, previously cleared as ActiveCare®++ under K060146.

7.1.8 Device Description:

The ActiveCare+SFT® is a prescriptive, pneumatic compression system designed to apply sequential compression to the lower limb. The control unit of the ActiveCare+SFT® is light and compact, thus making it a portable ambulant system. The ActiveCare+SFT® provide the user with an option of battery operation in addition to the operation from the mains option. The ActiveCare+SFT® is easy to use and provides the user with several treatment options: compression of the foot – single or double, compression of the calf – single or double, compression of the Thigh – single or double, and combined compression of any combination of two sleeves.
The foot compression program is intermittent pressure pulse application to a single celled foot sleeve. The calf and thigh compression program is a sequential intermittent application of a pressure to a three-celled cuff sleeve.

7.1.9 Intended Use:

The ActiveCare+SFT® System is a prescriptive device that induces Continuous Enhanced Circulation Therapy of the lower limbs.
The ActiveCare+SFT® System is intended for use in:

- Preventing Deep Vein Thrombosis (DVT).
- Enhancing blood circulation.
- Diminishing post-operative pain and swelling.
- Reducing wound-healing time.
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers.
- Treatment of chronic venous insufficiency.
- Reducing edema.

7.1.10 Contraindications:

The ActiveCare+SFT® System should not be used in the following cases: fresh pre-existing DVT, pulmonary embolism, leg gangrene, recent skin graft, acute thrombophlebitis and in medical situations where increased venous and lymphatic return is undesirable

7.1.11 Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the ActiveCare+SFT® System complies with the voluntary standards such as IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4 and ISO 14971.

7.1.12 Performance Data & Substantial Equivalence

The ActiveCare+SFT® System is substantially equivalent in all aspects, e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the commercially available Medical Compression Systems (DBN) Ltd.'s ActiveCare+SFT® System, previously cleared under K060146.
The difference between the modified and the cleared ActiveCare+SFT® system is that the new model incorporates a modified software module designed to collect and correlate data already being measured by the device to detect possible conditions that may be indicative of the development of venous flow obstruction in the treated legs of those patients receiving the prophylaxis treatment (i.e., Venous Obstruction Detection software module).

A series of performance testing, including bench testing and clinical comparison in healthy volunteers, were performed to demonstrate that the modified ActiveCare+SFT® System does not raise any new questions of safety and efficacy. These tests include:

- Software verification and validation
- Lab tests /Performance testing:
  Lab 003- Validation of the ActiveCare+SFT®'s Venous Obstruction Detection software module.

Based on these tests results, Medical Compression Systems (DBN) Ltd. believes that the modified ActiveCare+SFT® System is substantially equivalent to the cleared ActiveCare+SFT® System without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 12 2011

Medical Compression Systems (DBN) Ltd.
c/o Ms. Orly Maor
Company Consultant
25 A Sirkin Street
Kfar Saba
ISRAEL 44421

Re: K110159
Trade/Device Name: ActiveCare+SFT® System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compression Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: April 1, 2011
Received: April 5, 2011

Dear Ms. Maor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110159

Device Name: ActiveCare+SFT® System

Indications for Use:
The ActiveCare+SFT® System is a prescriptive device that induces Continuous Enhanced Circulation Therapy of the lower limbs.
The ActiveCare+SFT® System is intended for use in:

- Preventing Deep Vein Thrombosis (DVT).
- Enhancing blood circulation.
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- Treatment of chronic venous insufficiency.
- Reducing edema.

Prescription Use __√__ (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use____ (Part 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110159

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